



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

Contact Person: Patricia Harris

(916) 445-5014

LICENSING COMMITTEE

Hilton Oakland Airport

One Hegenberger Road

Oakland, CA 94621

(510) 635-5000

March 16, 2005

9:30 a.m. – 12 noon

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 working days prior to the meeting. Opportunities are provided to the public to address the committee on each agenda item. Board members who are not on the committee may also attend and comment.

- A. Call to Order 9:30 a.m.
- B. Proposed Statutory Changes to the Licensure and Regulation of Clinics
(Business and Professions Code sections 4180 –4186) and Surgical Clinics
(Business and Professions Code sections 4190-4195)
- C. Evaluation and Certification Process of Foreign Pharmacy Graduates by the Foreign Pharmacy Graduate Examination Committee (FPGEC) and the Test of Spoken English (TSE) Requirement
- D. Competency Committee Report:
- Licensure of New Pharmacists
 - New Contract for Administration of the California Pharmacy Jurisprudence Examination (CPJE)
 - Petition Process for Foreign Graduates for 600 Intern Credit for Experience in a Foreign Country
 - Report on the Accreditation Council for Pharmacy Education (ACPE) Site Visit to Loma Linda University and UCSD Schools of Pharmacy
- E. Development of Proposal for Pharmacist Performing Drug Utilization Review (DUR), Medication Therapy Management, Pharmacist Call Centers and Central Processing of Prescriptions for California Patients

Adjournment

12 noon

Meeting materials will be on the board's Web site by March 9, 2005

AGENDA ITEM B

Memorandum

To: Licensing Committee

Date: March 8, 2005

From: Anne Sodergren
Staff Services Manager
Board of Pharmacy

Subject: Recommendation to Revise Clinic Licensing Program

A clinic license issued by the board allows for the purchase of drugs at wholesale and allows for a common stock of dangerous drugs and devices that are then dispensed by authorized prescribers. Without a clinic license, each physician must maintain a separate drug supply.

Consistent with the board's Strategic Plan objective to review all licensing programs, board staff reviewed the board's licensing requirements for clinics. During the review several inconsistencies between the requirements for nonprofit or free clinics and surgical clinics were noted.

The attached statutory changes are recommended to streamline the application process, better define who is accountable for the license and make consistent the two types of clinic licenses issued by the board.

Below is a brief description of each of the changes.

Business and Professions Code Section (B & P) 4180

- Change the records retention from seven years to three years consistent with the pharmacy record retention requirement.
- Change the language to allow the board to change the location of a clinic license without issuing a new clinic license (change of permit).
- Require any change in ownership to be reported to the board.

B & P 4181

- Require the policies and procedures to be approved by representatives of health care professionals.
- Remove the requirement to detail the method used to develop the policies and procedures.

B & P 4182

- Remove the administrator as one of the mandatory reviewers of the policies and procedures.
- Require the consulting pharmacist to certify, in writing, quarterly if the clinic is operating in compliance with pharmacy law. These certifications shall be retained for three years.
- Require notification of a change in professional director.

B & P 4190

- Change the records retention from seven years to three years.
- Change the language to allow the board to change the location of a clinic license without issuing a new clinic license. (change of permit)
- Require any change in ownership to be reported to the board.

B & P 4191

- Require the policies and procedures to be approved by representatives of the health care professionals.
- Remove the requirement to detail the method used to develop the policies and procedures.

B & P 4192

- Require the clinic to retain a consulting pharmacist to review the policies and procedures.
- Require the consulting pharmacist to certify in writing quarterly if the clinic is operating in compliance with pharmacy law. These certifications shall be retained for three years.
- Defines "professional director."
- Require notification of a change in professional director.

Article 13- Nonprofit or Free Clinics

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of ~~seven~~ three years for inspection by all properly authorized personnel.

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. ~~Each license shall be issued to a specific clinic and for a specific location.~~ A separate license shall be required for each of the premises of any person operating a clinic in more than one location.

(c) Any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

4181. (a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Health Services relating to the drug distribution service to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by health care professionals including the consulting pharmacist, the professional director, physicians and registered nurses. ~~and the clinic administrator.~~

~~(b) These policies and procedures shall include a written description of the method used in developing and approving them and any revision thereof.~~

(c) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4182. (a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director ~~and the administrator~~. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify ~~in writing least twice a year~~ quarterly that the clinic is, or is not, operating in compliance with the requirements of this article, ~~and the most recent of those written certifications shall be submitted with the annual application for the renewal of a clinic license.~~ Each written certification shall be kept on file in the clinic for three years after it is performed and shall include corrective actions recommended if appropriate.

(c) For the purposes of this article, "professional director" means a physician acting in his or her capacity as medical director.

(d) Any person who has obtained a license to conduct a clinic shall notify the board within 30 days of a change in professional director.

Article 14 – Surgical Clinics

4190. (a) Notwithstanding any provision of this chapter, a surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic, as provided in subdivision (b). The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of ~~seven~~ three years for inspection by all properly authorized personnel.

(b) The drug distribution service of a surgical clinic shall be limited to the use of drugs for administration to the patients of the surgical clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(c) No surgical clinic shall operate without a license issued by the board nor shall it be entitled to the benefits of this section until it has obtained a license from the board. ~~Each license shall be issued to a specific clinic and for a specific location.~~ A separate license shall be required for each of the premises of any person operating a clinic in more than one location.

(d) Any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

4191. (a) Prior to the issuance of a clinic license authorized under this article the clinic shall comply with all applicable laws and regulations of the State Department of Health Services and the board relating to drug distribution to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. These policies and procedures shall include a written description of the method used to develop, approve, and revise those policies and procedures. The policies and procedures to implement the laws and regulations shall be developed and approved by health care professionals including the consulting pharmacist, the professional director, physicians and registered nurses.

(b) The dispensing of drugs in a clinic that has received a license under this article shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4192. Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing least quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each written certification shall be kept on file in the clinic for three years after it is performed and shall include corrective actions recommended in appropriate.

(c) For the purposes of this article, "professional director" means a physician acting in his or her capacity as medical director.


(d) Any person who has obtained a license to conduct a clinic shall notify the board within 30 days of a change in professional director.

AGENDA ITEM C

Memorandum

To: Licensing Committee

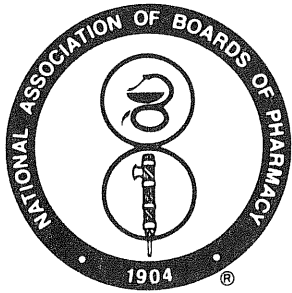
Date: March 4, 2005

From: Patricia F. Harris 
Executive Officer

Subject: **Foreign Pharmacy Graduate
Committee (FPGEC) Certification
Program**

Last year the board sponsored an omnibus provision in SB 1913 (Business and Professions Committee, Chapter 695, Statutes of 2004) that requires certification by the FPGEC as an application requirement for foreign-educated pharmacists seeking licensure in California. This requirement took effect January 1, 2005.

Attached is an overview of the certification process. Also included is a memorandum from the National Association of Boards of Pharmacy (NABP) regarding the Test of Spoken English (TSE) that is required as part of the FPGEC certification process. California has required the TSE since 1991, and amended its regulation to require it of those foreign pharmacy graduates who were FPGEC certified prior to January 1, 1998.



National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014

Tel: 847/391-4406 • Fax: 847/391-4502

Web Site: www.nabp.net

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
FROM: Avery L. Spunt, MEd, RPh, FASHP, Competency Assessment Director
DATE: February 11, 2005
RE: Foreign Pharmacy Graduate Examination Committee

The Foreign Pharmacy Graduate Examination Committee (FPGEC) operates under the auspices of NABP to evaluate the qualifications of foreign pharmacy graduates who apply for FPGEC certification. NABP receives applications from candidates from over 130 countries. At times the evaluation process is delayed for an extended period of time for many different reasons, some of which include:

- candidates not following the application process as described in the *FPGEC Certification Program Application/Registration Bulletin*;
- documents submitted incorrectly;
- name changes; or
- lack of cooperation from the candidate's country of origin or institution from which they graduated.

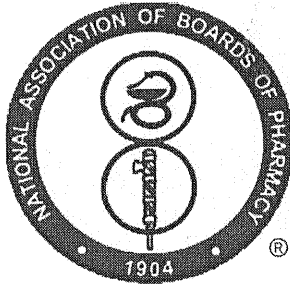
Not all candidates have the qualifications to be approved and, therefore, not accepted. In recent years the FPGEC has also had the responsibility of assuring the authenticity of documents as well as assuring the individuals are who they say they are. This has become a necessity as NABP has found that a number of candidates submit fraudulent and/or counterfeit documents. This increased vigilance is essential to protect the health and welfare of the public as well as essential to homeland security. Unfortunately, some legitimate candidates are substantially delayed due to issues pertaining to authenticity of documentation. The FPGEC processes candidates' files as quickly as possible, while maintaining the public health and safety.

The FPGEC would like to share with you some of the steps taken during the evaluation process:

1. The application/registration form is considered a legal document; therefore, it is carefully reviewed to assure that the information it contains is correct and that it has been properly executed.
2. Verification is made that the affirmation statement has been properly completed.
3. Verification is made that the candidate's photographs have been submitted according to procedures.
4. The candidate's name and date of birth must match exactly on all of his or her supporting documentation as to the information provided on his or her application/registration form. Any discrepancies in a name or date of birth must be explained and properly documented.
5. Transcripts and syllabuses are reviewed and verified to assure that candidates are graduates of four-year pharmacy curriculum for candidates earning their degree prior to January 1, 2003; or a five-year pharmacy curriculum for those earning their degree after January 1, 2003.
6. It is verified that the candidate graduated from a recognized pharmacy program in his or her country.
7. It is verified that the candidate's degree has actually been awarded.
8. It is verified that documentation of the candidate's licensure and/or registration to practice pharmacy in the country where his or her pharmacy degree was earned.
9. It is verified that all supporting documentation of a candidate's pharmacist credentials has been submitted to the FPGEC according to the procedures indicated in the *Application/Registration Bulletin* that have been established as a safeguard against fraudulent documentation.
10. It is verified that the documents received were submitted by the appropriate issuing bodies, and that the proper officials have signed and/or sealed the document.
 - a. Documents that are not in English, including any seals or stamps affixed to the document, must be accompanied with a word-for-word English translation.
 - b. A translation is carefully reviewed for completeness.
11. It is verified that proper documentation of the translator's credentials has been provided.
12. Verify receipt of official Test of English as a Foreign Language (TOEFL) and Test of Spoken English (TSE) score reports.
13. Verify that the TOEFL and/or TSE has been taken within the designated time frame and that the minimum passing score has been attained as indicated in the *Bulletin*.

The FPGEC will continue to process candidates' files as quickly as possible while maintaining the public health and safety. Should you have any questions with regard to this matter, please contact me at 847/391-4400 or via e-mail at aspunt@nabp.net.

CC: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary
Mary A. Dickson, Associate Executive Director



nabp

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

DATE: February 18, 2005

RE: **FPGEC - State Waivers**

NABP is aware that a few states are struggling with requests from candidates seeking certification through NABP's Foreign Pharmacy Graduate Equivalence Certification (FPGEC) program to waive the requirement for the Test of Spoken English (TSE). In cases discussed with NABP, candidates have not been able to successfully complete the TSE portion of the English proficiency component of FPGEC. One example shared with NABP was a candidate who sat for the TSE on more than one occasion and received the same score, a score below the passing standard accepted by NABP. The candidate maintains that there must be a problem with the assessment or the standard recognized by NABP.

In order to help boards of pharmacy understand the situation and respond to requests and questions from candidates, we are providing the following information to you:

- The number of candidates expressing concern with the TSE is extremely low. Of the 4,000 individuals tested in 2004, approximately 80% of the candidates for certification successfully completed the TSE on the initial attempt. The number of candidates passing TSE after subsequent attempts increases the passing percentage slightly. The number of candidates of all the candidates examined in the past few years raising concerns with the TSE standard recognized by NABP, that we are aware of, is 30;
- The TSE standard recognized by NABP was established through a valid and defensible standard setting process overseen by the Educational Testing Services (ETS) and NABP's competence assessment and psychometric committees, policies and staff;
- The passing standard recognized by NABP is also recognized by other health care professions, medicine, nursing, physical and occupational therapists. In fact, the TOEFL requirements for occupational and physical therapists are actually more stringent than the standard recognized by NABP.

EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

February 18, 2005

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The NABP Executive Committee will be asking the Advisory Committee on Examinations (ACE) to review the TSE standard recognized by NABP and report back to the Executive Committee. NABP is also working with ETS and the professions of nursing, physical therapy, and occupational therapy to redesign the English proficiency assessment and perhaps establish one standard for health care professionals that interact and communicate with patients and other health care professionals.

NABP asks the boards to exercise extreme caution in granting waivers to the English proficiency standards recognized by NABP. Clearly, the boards have the authority to issue waivers for such requirements. However, unless the board has the expertise or has conducted an objective and valid standard setting process similar to that which NABP used and uses for all of its assessment programs, the board could be placing itself in a position where the board's actions to over ride a valid standard are viewed as subjective and arbitrary. It could also open the board to some increased liability.

NABP also shares with the boards that communication problems are a significant cause of medication errors. At the NABP/AACP District Meetings this past year, a theme repeated at almost every meeting was the increasingly high number of complaints concerning medication errors that the boards are receiving and that can be attributed to inadequate communication skills of the pharmacists. Some boards and districts have suggested that NABP develop an English proficiency standard that all pharmacists would be required to complete prior to licensure. In light of the concerns voiced by the boards and the documented examples of communication problems, we again urge the boards to proceed cautiously in granting waivers in areas where valid standards have been established.

Thank you for your consideration.

CC/mwg

cc: NABP Executive Committee

AGENDA ITEM D

Memorandum

To: Licensing Committee

Date: March 2, 2005

From: Virginia Herold

Subject: Competency Committee Report

1. Report on the Pharmacist Licensure Examinations

The board transitioned to the new examination structure in January 2004. The board began administering the California Pharmacist Jurisprudence Examination (CPJE) in March 2004.

Here are statistics describing our examination program as of February 28, 2005:

2,778 applications have been received to take the California license exams

1,341 individuals have become licensed as pharmacists since mid-June

2,195 individuals have been made eligible to take the licensure examinations

1,731 individuals have been verified to the NABP as qualified to take the NAPLEX for California (includes score transfers)

1,990 CPJE examinations have been administered

357 failed CPJE examinations

82 regrades of the CPJE have been performed (resulting in no change in score)

The CPJE's pass rate is 85 percent

2. Restructuring of the Competency Committee

The Competency Committee develops and scores the CPJE. One year ago, at the April Board Meeting, the board agreed with a Licensing Committee recommendation to restructure the Competency Committee into a two-tier structure – a core committee and a group of item writers.

The item writers will develop questions for the examination, and the core committee will select items and refine them for the examination, select cut scores and oversee issues arising from administration of the examination.

To activate this restructuring, the board needs additional pharmacists to serve as item writers and committee members. The board is now aggressively recruiting individuals for these important duties. The board's January 2005 newsletter, (the first since the restructuring was approved) requests interested individuals to submit applications. All board members are asked to assist in recruiting for these positions.

The item writers will meet once annually for an item-writing workshop. Then, throughout the year, assignments to write questions in specific areas of the content outline will be assigned. There will be no other meeting for this group of individuals.

The core committee will be slightly smaller than the current Competency Committee (if the current Competency Committee was fully appointed, there would be 29 members). The new structure is:

<u>Composition:</u>	<u>19 members</u>
Schools of Pharmacy: 1 member each	6 members
Community Practice:	6 members
Institutional Practice:	5 members
Board Member:	1 member
Inspector:	1 member

Attendance of the core committee meetings will be a requirement, and those who miss a certain number of committee meetings each year will be asked to become item writers, where attendance at meetings is not necessary. There will be six two-day meetings annually.

The preference for members of both committees would be for pharmacists who are more recent graduates of pharmacy schools instead of long-term practicing pharmacists, although some experienced pharmacists are also needed. Newer pharmacists are sought because the examination measures practice at the entry level with two years' pharmacist experience, not after 20 years of experience.

Appointment to the committee or as an item writer is an honor and an opportunity to give back to the profession. It is also a good opportunity to learn more about Pharmacy Law. Committee members are paid \$30 per hour to perform committee duties.

The board's president will appoint members to the committees. To apply for appointment, an applicant needs to submit one CV/resume and three letters of reference. This material needs to be submitted to the board (Competency Committee Appointments, Board of Pharmacy, 400 R Street, Suite 4070, Sacramento, CA 95814).

3. Job Analysis Underway

The board is required to perform a job analysis of the pharmacist profession every three to five years, to maintain the validity of the licensure examination. The Department of Consumer Affairs recommends that a job analysis be conducted every five years. The job analysis identifies the skills, frequency and importance of tasks performed by pharmacists. From these skill statements, the Competency Committee develops a content outline for the examination. All questions for the examination are developed according to this outline.

The board completed its last job analysis in 1999/00.

In late November 2004, the board mailed a job analysis questionnaire to 3,000 California pharmacists. By the deadline for submission (December 31, 2004), approximately 1,200 responses were received (a 40 percent return response).

The pharmacists surveyed by the board were asked to identify the tasks that they perform, and the frequency and the importance of the tasks. The responses will be tallied by the board's examination consultant and analyzed by the Competency Committee in August. A new content outline should be in place by the end of 2005. Before the new content outline will be implemented, it will be released publicly so that candidates can prepare for the examination. The board's CPJE content outline will not include tasks tested by NAPLEX; these tasks will be removed via analysis of the NAPLEX content outline.

4. New Contract Underway for Administration of the California Pharmacy Jurisprudence Examination

The board's CPJE is administered through Experior Assessments, LLC, at test centers nationwide. Experior also administers California examinations for many other boards and programs of the Department of Consumer Affairs. There is a master contract for these test administration services, which is a convenience to all departmental entities because we do not each need to go out to bid for separate test administration contracts. However, this master contract ends November 30, 2005.

Currently the Department of Consumer Affairs is preparing a request for proposals (RFP) for test administration services for the future. The successful vendor will provide test administration services for the department's entities for the next five years.

At this time, the tentative RFP release date is April 4th. Review of the responses to the RFP by the evaluation team will be completed by May 4. The new contract should be awarded on June 20, 2005, leaving four months to implement a transition to the new contract before the end of the current contract.

Delays in this process could impact the ability of applicants to take the CPJE after November 30, 2005. The board's staff is participating in the RFP process and carefully following the timelines to assure there are no administration problems in December.

5. Petition Process for Foreign Graduates for 600 Intern Hours for Experience Earned in a Foreign Country

For a number of years, pharmacist interns have been required to earn 1,500 hours of intern experience as a requirement for pharmacist licensure. The only exception was for pharmacists licensed in other states who could meet this requirement by providing evidence of licensure and working as a pharmacist for one year in another state.

Last year's board omnibus bill (SB 1913, Chapter 695) contained provisions that moved key intern requirements from board regulations to statutes. At the January 2005 Board Meeting, the board approved adoption of a related rulemaking to streamline the requirements for earning intern hours. Several changes were made, including one to eliminate a cap of 250 hours on maximum intern hours earned during the first year of pharmacy school. The final version of the regulation follows this memorandum and should be in effect about July 1, 2005.

Since before 1990, the board has had an informal process to allow pharmacists from foreign countries to petition for 600 intern hours for experience they earned in the foreign country as an intern or pharmacist. To petition for the 600 hours, the applicants had to have earned 250 hours of intern experience in California, and provide experience affidavits attesting to their experience in the foreign country. The board used the old intern experience affidavits and required an estimate of how many hours the applicant spent performing the specific duties in the foreign country.

The core of this evaluation was the assumption that the time spent performing the duties on the experience affidavit in the foreign country (e.g., processing prescriptions) would be the same as when performed in California. There was no other validation for this assessment. Members of the Competency Committee would review these experience petitions. Anyone who worked with the individual from the foreign country could sign the affidavit, although the board preferred that a pharmacist do it. Typically fewer than 10 of these petitions are received annually.

The problem is that the petition process outlined above is an underground regulation, and the board cannot continue with this process unless a regulation is promulgated to permit it.

The committee needs to consider whether it wishes to recommend that the board continue this process, or disband it. To put a regulation in place will take approximately nine –12 months.

6. Report on Site Visits by the Accreditation Council for Pharmacy Education to the Schools of Pharmacy at Loma Linda University and UCSD

Over the last few months, the ACPE has visited the new schools of pharmacy at Loma Linda University and the University of California San Diego. Chairperson Conroy participated in the review at the Loma Linda School of Pharmacy, and Board Member Schell participated in the review at UCSD.

During the committee meeting, Chairperson Conroy will provide a description of the review.

As Proposed by Board Rulemaking Underway:

~~§1728. Intern Experience—Requirements for Examination. Licensure.~~

- ~~(a) Minimum Hours: All intern pharmacists must complete 1,500 hours of experience as a prerequisite to licensure.~~
 - ~~(1) First Year Maximum: A maximum of 250 of the 1,500 hours may be obtained during the first year of pharmacy education in a program sponsored by a school of pharmacy recognized by the Board.~~
 - ~~(2) Preceptor Supervision: A minimum of 900 of the required 1,500 hours must be obtained in a pharmacy under the supervision of a preceptor.~~
 - ~~(3) Board Approved Experience: A maximum of 600 of the required 1,500 hours may be granted at the discretion of the Board for other experience which substantially relates to the practice of pharmacy.~~
- ~~(b) Required Areas of Experience: Effective January 1, 1986 all applicants for licensure must complete experience in both community pharmacy and institutional pharmacy practice in settings in the following areas:~~
 - ~~(1) Receiving and interpreting the prescription;~~
 - ~~(2) Patient medication profiles;~~
 - ~~(3) Prescription preparation;~~
 - ~~(4) Consultation;~~
 - ~~(5) Record keeping;~~
 - ~~(6) Over the counter products;~~
 - ~~(7) Drug information.~~
- ~~(c) Proof of Experience: All intern pharmacists are required to submit proof of their experience on Board approved affidavits which shall be certified by the preceptor under whose immediate supervision such experience was obtained.~~
- ~~(d) Out of State Exemption: One who is licensed as a pharmacist in any state and who has practiced as a pharmacist in that state for at least one year, as certified by the Board of Pharmacy of that state, shall be exempt from the pharmaceutical requirements of this section.~~
- (a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:
 - (1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
 - (A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
 - (B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.
 - (C) Experience in both community pharmacy and institutional pharmacy practice settings.
 - (D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.
 - (2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

- (3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.
- (4) A signed copy of the examination security acknowledgment.
- (b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.
- (c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

AGENDA ITEM E

Memorandum

To: Licensing Committee

Date: March 3, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Development of Proposal for
Pharmacists Performing Drug
Utilization Review (DUR), Medication
Therapy Management (MTM),
Pharmacist Call Centers and Central
Processing of Prescriptions for CA
Patients**

At the last Licensing Committee meeting, staff prepared an overview of the many issues and questions that the board has received regarding pharmacist's care and the practice of pharmacy for California patients. The purpose of the document was to provide the foundation to begin the discussion on how the board should address these many issues that do not fit the traditional statutory definition of pharmacy and the independent practice of pharmacists as health care professionals.

There was considerable discussion. The committee agreed to address the various issues through its quarterly meetings. However, the committee was encouraged to develop a proposal sooner than later as the provisions of the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act take effect in 2006. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide MTM for Medicare beneficiaries. Examples of MTM services are: patient health status assessments; medication "brown bag" reviews; formulating/adjusting prescription treatment plans; patient education and training; collaborative drug therapy management; special packaging; refill reminders; and other pharmacy related services.

The following is a summary of the proposed statutory changes to address the issues that were provided to the Licensing Committee at its last meeting. (**Attachment 1**)

Section 4036 - This change updates the definition of pharmacist.

Section 4037 – This change updates the definition of a pharmacy to include an “intake/dispensing pharmacy”, a “prescription processing pharmacy”, an “advice/clinical care pharmacy” and “nonresident pharmacy”. These pharmacy types are not mutually exclusive. In addition, the definition of pharmacy excludes clinics licensed by the board.

Section 4050 – This change acknowledges that pharmacy is an evolving profession that includes more sophisticated and comprehensive patient care activities.

Section 4051 – This change is to update pharmacy law to accurately reflect pharmacy practice and the functions of a pharmacist. It also requires that a pharmacist who performs cognitive services for California patients be licensed in California. Additionally, it specifies that a pharmacist who authorizes the initiation of a prescription or performs other cognitive services outside a licensed pharmacy must maintain patient records or other patient-specific information used in those activities and the records must be provided to the board upon request.

Section 4052, 4052.1, 4052.2 and 4052.3 – These changes are technical clean up of these statutes to make them easier to read and understand. These sections provide for pharmacists’ collaborative practice with a physician pursuant to a protocol. There is no change to the scope of practice for pharmacists, the protocol or the emergency contraception drug therapy requirements.

Section 4112 – This change updates the definition of a nonresident pharmacy to include prescription review, patient consultation drug utilization review, medication therapy management and other cognitive pharmacy services. Requires that the pharmacist-in-charge of a nonresident pharmacy be a California licensed pharmacist. Requires that only a California licensed pharmacist can perform prescription review, consultation, drug utilization review, medication therapy management or other cognitive pharmacy services for California patients.

Section 4113 – This change updates the requirements for the pharmacist-in-charge and clarifies the board authority to deny an application for a pharmacist-in-charge.

Section 4125 – This change requires a pharmacy to include in its quality assurance program not only the documentation of medication errors, but also inappropriate provision of cognitive services such as prescription review, consultation, and drug utilization review or medication therapy management.

Section 4207 – This change includes the board’s authority to investigate matters related to the performance or provision of cognitive services.

Section 4306.5 – This change adds to the definition of unprofessional conduct for a pharmacist those acts or omissions that involve the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regard to dispensing or furnishing controlled substances, dangerous drugs or dangerous devices and/or with regard to the provision of cognitive services. It also includes the acts or omissions that involve the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function. For pharmacists that practice outside of a licensed pharmacy premise, unprofessional conduct may include acts or omissions that involve the failure to fully maintain

and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

Attachment 2 has the background documents from the last meeting that framed the issues.

Issue 1

This issue addressed the central processing of prescriptions by California licensed pharmacies. In this situation, Pharmacy A sends a prescription electronically or via fax to its other Pharmacy B for input into its computer system to generate a prescription label. A pharmacist at Pharmacy B reviews and analyzes the prescription, performs drug utilization review and other cognitive activities required to confirm that the prescription is appropriate. The pharmacist at Pharmacy B approves the filling of the prescription and the confirmation is sent to Pharmacy A to fill the prescription and dispense it. A pharmacist at Pharmacy A performs final verification, and dispenses/consults. The assumption is that both these pharmacies have common ownership and electronic prescription files.

In this situation, central processing of a prescription is performed in a licensed California pharmacy that also dispenses prescriptions and the cognitive services are performed by licensed California pharmacists either in the pharmacy or by access to the information pursuant to Business and Professions Code section 4051, subdivision (b).

Appropriate licensed entities and personnel are performing the functions as required and authorized by California pharmacy law. This process is different from the refill and central fill processes authorized by California Code of Regulations, title 16, sections 1707.4 and 1710.

It is the corresponding responsibility of every pharmacist and/or pharmacy filling a prescription to ensure legitimacy, propriety, and accurate dispensing.

The Licensing Committee didn't have an issue with this situation.

Issue 2

In this example, a prescription is sent electronically or via fax to a central facility to process the prescription and perform drug utilization review. This central facility is located in California and California licensed pharmacists are performing the review. This facility doesn't dispense prescription drugs. Once approved, the prescriptions are dispensed by a licensed pharmacy that may or may not have a shared ownership and common electronic prescription files with the central prescription processing facility.

The central processing facility would fit the definition of proposed Business and Professions Code section 4037(a)(2). It would be considered a prescription processing pharmacy.

Issue 3

This scenario is related to a prescription that originates in California. It is sent electronically or via fax to an out-of-state central prescription processing facility. The out-of-state central prescription processing facility inputs the prescription label information and a pharmacist (who may or may not be licensed in California) performs drug utilization review. The prescription is

filled and dispensed at a California pharmacy or through a California licensed nonresident pharmacy. Also, within the central prescription process facility, there may be a Call Center, where California patients can talk to a pharmacist and receive pharmacist's services. In some instances, a Call Center may be stand-alone and not part of a central prescription processing facility.

It was noted that the out-of-state central prescription processing facility may or may not be licensed in its resident state as a pharmacy. If it is licensed as a pharmacy in its resident state, the pharmacy does not meet the definition of a California nonresident pharmacy in that the pharmacy doesn't ship, mail or deliver controlled substances, dangerous drugs, or dangerous devices into California.

The proposal would require that this pharmacy be licensed as a "nonresident pharmacy" and would require that the pharmacist-in-charge and the pharmacists performing drug utilization review and/or any other cognitive pharmacy services for California patients be licensed as well.

Issue 4

The fourth example that was presented was about a database for California pharmacies that is maintained in or through a regional call center located and managed in another state. This regional call center is a licensed pharmacy in that state and is supervised by a licensed pharmacist from that state. It is unknown if this licensed pharmacy also dispenses dangerous drugs, either within its state or to California patients. The database identifies non-preferred drugs. These non-preferred drugs are identified for evaluation and consideration for therapeutic interchange and conversion to the company's preferred drug. The goal is to switch equally effective medications within a class to alternatives that are less costly.

A California licensed pharmacist reviews and approves the therapeutic interchange of a non-preferred drug with that of a preferred drug. Once approved by the California licensed pharmacist, the prescription is faxed to the California physician for approval or rejection. The physician faxes back the approval or denial to the out-of-state regional call center where the database is updated.

For this scenario, the out-of-state pharmacy would be required to be licensed in California as a non-resident pharmacy. The pharmacist-in-charge and any pharmacists performing cognitive services would also be required to be licensed in California.

Issue 5

The last situation is the new provision in the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide Medication Therapy Management (MTM) for Medicare beneficiaries. Examples of MTM services are: patient health status assessments; medication "brown bag" reviews; formulating/monitoring/adjusting prescription treatment plans; patient education and training; collaborative drug therapy management; special packaging; refill reminders; and other pharmacist related services.

It was noted in the comments provided by the National Association of Boards of Pharmacy (NABP) to the Centers for Medicare & Medicaid Services on the proposed regulations to implement the MMA, that NABP was not clear on how states will view the provision of MTMP's across state lines.

The proposal amends Business and Professions Code section 4051, updating the authority and responsibility of pharmacists performing functions related to the practice of pharmacy so as to encompass many of the MTM services. The proposal also requires that a pharmacist performing these functions for California patients be licensed in California. This section of law currently authorizes a pharmacist outside of a licensed pharmacy to provide cognitive services, clinical advice or information and patient consultation.

Medco will be providing a brief presentation on its alternative pharmacy practice site.
(Attachment 3)

Attachment 4 is a written comments submitted by Omnicare supporting a concept for requiring a contract between a California licensed pharmacy and its Regional Clinical Center. In addition, Omnicare is requesting that the board move quickly as the Medicare Modernization Act and Part D Medicare are scheduled to being January 2006.

ATTACHMENT 1

Proposed Scope of Practice Revisions – Licensing Committee March 16, 2005

§ 4036. Pharmacist

"Pharmacist" means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of a valid, unexpired pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy as authorized by this chapter.

§ 4037. Pharmacy

(a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced ~~and where prescriptions are compounded.~~ The profession of pharmacy may be practiced in diverse settings, including the following:

(1) "Intake/dispensing pharmacy" means an area, place, or premises licensed by the board in which "Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail by personnel licensed by the board.

(2) "Prescription processing pharmacy" means an area, place, or premises licensed by the board in which personnel licensed by the board engage in and/or supervise drug order/prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient and/or prescriber contact, claims submission and processing, patient profile review, and allergy and drug-interaction review, but in which controlled substances, dangerous drugs, or dangerous devices are not stored, possessed, prepared, derived, compounded, nor repackaged, and from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(3) "Advice/clinical center pharmacy" means an area, place, or premises licensed by the board in which personnel licensed by the board provide cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, and medication therapy management, but in which controlled substances, dangerous drugs, or dangerous devices are not stored, possessed, prepared, derived, compounded, nor repackaged, and from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(4) "Nonresident pharmacy" means an area, place, or premises licensed by the board that is located outside this state, that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state, and/or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state. It may be any or all of types (a)(1) to (a)(3).

(b) These pharmacy types are not mutually exclusive.

(c) Unless otherwise specified, whenever the term “pharmacy” is used in this chapter, it shall be deemed to refer to every one of the types in (a)(1) to (a)(4). Unless otherwise specified, each requirement made applicable to any pharmacy by this chapter is applicable to all.

~~(b)~~(d) "Pharmacy" shall not include any area in a facility licensed by the State Department of Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

(e) “Pharmacy” shall not include any of those clinics listed in Section 4180 or Section 4190.

§ 4050. Professional status

(a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

§ 4051. ~~Dangerous drugs and devices~~Pharmacy practice

(a) The holder of a valid, unexpired pharmacist license issued by the board is vested with the authority and responsibility to perform the following functions inherent to pharmacy practice:

- (1) Interpreting, verifying, and implementing drug orders and prescriptions;
- (2) Dispensing pursuant to legitimate drug orders and prescriptions;
- (3) Ensuring proper drug storage, documentation, labeling and record-keeping;
- (4) Maintaining accurate, complete, and confidential patient profiles and records;
- (5) Supervising pharmacy technicians and other ancillary personnel in the pharmacy;
- (6) Designing and implementing quality assurance procedures and protocols;
- (7) Compounding drug products pursuant to prescription and for prescriber office use;
- (8) Maintaining safe, secure, and sanitary conditions in licensed premises;
- (9) Performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation;
- (10) Collaborating with prescribers and other care providers regarding patient care;
- (11) Implementing standardized procedures and protocols regarding patient care;
- (12) Administering or furnishing drugs or biologicals where permitted by law;
- (13) Initiating, adjusting, or implementing patient drug regimens where permitted by law; and
- (14) Such other pharmacy functions as are authorized by this chapter.

(ab) Except as otherwise provided in this chapter, it is unlawful for any person to ~~manufacture~~, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist licensed under this chapter.

(c) Except as otherwise provided in this chapter, it is unlawful for any person to perform any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, unless he or she is a pharmacist licensed under this chapter.

(bd) Notwithstanding any other law, a pharmacist licensed under this chapter may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide cognitive services, clinical advice or information, or patient consultation, if all of the following conditions are met:

(1) The cognitive service, clinical advice or information, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of cognitive services, patient and clinical consultation, and advice, and appropriately reviews that information before performing any of these functions.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

(4) A pharmacist authorizing the initiation or adjustment of a prescription, providing clinical advice or information or patient consultation outside the premises of a licensed pharmacy shall maintain the patient records or other patient-specific information used in those activities in a readily retrievable form and provide those records to the board upon request. These records or information shall be preserved for a period of at least three years from the date they were relied upon or consulted by for the purposes of performing any such function.

§ 4052. Power to perform procedures and functions; training

(a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded ~~medication~~ drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform ~~the following procedures or functions in a licensed health care facility as authorized by Section 4052.1. in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:~~

~~(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(B) Ordering drug therapy-related laboratory tests.~~

~~(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.~~

(5)(A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

~~(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(ii) Ordering drug therapy-related laboratory tests.~~

~~(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.~~

~~(B) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.~~

~~(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:~~

~~(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.~~

~~(ii) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.~~

~~(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.~~

~~(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.~~

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide cognitive services such as drug utilization review, medication therapy management, consultation to patients, and professional information, including clinical or pharmacological information, advice, or consultation, to other health care professionals.

(8)(A) Furnish emergency contraception drug therapy in accordance with either of the following as authorized by Section 4052.3.:

(9) Administer immunizations under the supervision of a prescriber.

~~(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.~~

~~(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.~~

(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

~~(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over the counter products by the federal Food and Drug Administration.~~

~~(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.~~

~~(b)(1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.~~

~~(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.~~

~~(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.~~

~~(be) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.~~

~~(cd) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.~~

(de) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

§ 4052.1. Performance of procedures or functions in a licensed health care facility; requirements

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

§ 4052.2. Performance of procedures or functions authorized by other providers; requirements

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery.

§ 4052.3. Furnishing emergency contraception drug therapy; requirements

(a) Notwithstanding any other provision of law, a pharmacist furnish emergency contraception drug therapy in accordance with either of the following:

(1) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(2) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(b) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(c) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(d) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this section.

(e) For each emergency contraception drug therapy initiated pursuant to this section, the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services,

the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

§ 4052.41. Skin puncture

Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

§ 4110. Licenses; renewal; transfer; temporary permits; fees

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit to conduct a pharmacy. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

§ 4112. Nonresident pharmacies; registration; prerequisites and requirements; fee; application; contact lenses

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state, and/or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state, shall be considered a nonresident pharmacy.

(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall comply with Section 4113.

(ef) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(g) Any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services performed by a nonresident pharmacy for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, may only be performed by a pharmacist licensed under this chapter.

(fh) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(gi) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(hj) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

~~(i) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.~~

(jk) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

§ 4113. Pharmacists-in-charge; designation; responsibilities; notifications

(a) Every pharmacy shall designate a pharmacist-in-charge, and shall not operate as a pharmacy without a designated pharmacist-in-charge. ~~and w~~Within 30 days thereof a new or replacement designation, the pharmacy shall notify-submit an application for approval of this designation to the board stating in writing of the identity and license number of that the designated pharmacist-in-charge, pharmacist and the date he or she was designated. The designated pharmacist-in-charge must have a valid, unexpired pharmacist license issued by the board. Where a designated pharmacist-in-charge has been denied a license, had a license revoked, suspended, or placed on probation, or is the subject of an ongoing board investigation into possible unprofessional conduct, the board may prospectively refuse or retroactively withdraw its approval of the designation and require that the pharmacy designate another pharmacist-in-charge.

(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

(c) Every pharmacy shall notify the board within 30 days of the date when a pharmacist ceases to be a pharmacist-in-charge. This duty is separate from and additional to that stated in subpart (a).

§ 4120. Nonresident pharmacies; registration; application forms; legislative intent

(a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler pursuant to this chapter without registering as a nonresident pharmacy.

(b) Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.

(c) Each application to conduct a nonresident pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037.

(ed) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.

~~(de)~~ The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to serve as any evidence that the nonresident pharmacy is doing business within this state.

§ 4122. Consumer information; posting or written receipts; prices

(a) In every pharmacy there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers a notice provided by the board concerning the availability of prescription price information, the possibility of generic drug product selection, and the type of services provided by pharmacies. The format and wording of the notice shall be adopted by the board by regulation. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy.

(b) A pharmacist, or a pharmacist's employee, shall give the current retail price for any drug sold at the pharmacy upon request from a consumer, however that request is communicated to the pharmacist or employee.

(c) If a requester requests price information on more than five prescription drugs and does not have valid prescriptions for all of the drugs for which price information is requested, a pharmacist may require the requester to meet any or all of the following requirements:

(1) The request shall be in writing.

(2) The pharmacist shall respond to the written request within a reasonable period of time. A reasonable period of time is deemed to be 10 days, or the time period stated in the written request, whichever is later.

(3) A pharmacy may charge a reasonable fee for each price quotation, as long as the requester is informed that there will be a fee charged.

(4) No pharmacy shall be required to respond to more than three requests as described in this subdivision from any one person or entity in a six-month period.

(d) This section shall not apply to a nonresident pharmacy, or to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel.

(e) Notwithstanding any other provision of this section, no pharmacy shall be required to do any of the following:

(1) Provide the price of any controlled substance in response to a telephone request.

(2) Respond to a request from a competitor.

(3) Respond to a request from an out-of-state requester.

§ 4125. Quality assurance program

(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors and/or inappropriate provision of cognitive services such as prescription review, consultation, drug utilization review, or medication therapy management attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications, or providing cognitive services, so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

~~(c) This section shall become operative on January 1, 2002.~~

§ 4201. Contents of applications; fees; powers of license holders

(a) Each application to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) Each application to conduct a pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037.

(b~~c~~) As used in this section, and subject to subdivision (ed), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(ed) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(de) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(ef) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(fg) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(gh) Notwithstanding any other provision of law, the wholesale license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(hi) Notwithstanding any other provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(ij) For licenses referred to in subdivisions (fg), (gh), and (hi), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

~~(j) This section shall become operative on July 1, 2001.~~

§ 4207. Investigations; limitations; requests for additional information

(a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices, or to the performance or provision of cognitive services, that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedures Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

§ 4306.5. Acts or omissions constituting unprofessional conduct

(a) Unprofessional conduct for a pharmacist may include:

(1) -Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board;

(2) -Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices and/or with regard to the provision of cognitive services;

(3) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(b) For pharmacists who practice outside of a pharmacy premises, unprofessional conduct may include acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

ATTACHMENT 2

ISSUE 1

Central Processing of Prescriptions by California Licensed Pharmacies

Scenario: Pharmacy A sends a prescription electronically or via fax to its other Pharmacy B for input into its computer system to generate a prescription label. A pharmacist at Pharmacy B reviews and analyzes the prescription, performs drug utilization review and other cognitive activities required to confirm that the prescription is appropriate. The pharmacist at Pharmacy B approves the filling of the prescription and the confirmation is sent to Pharmacy A to fill the prescription and dispense it. A pharmacist at Pharmacy A performs final verification, and dispenses/consults. The assumption is that both these pharmacies have common ownership and electronic prescription files.

Discussion:

Under this scenario, central processing of a prescription is performed in a licensed California pharmacy that also dispenses prescriptions and the cognitive services are performed by licensed California pharmacists either in the pharmacy or by access to the information pursuant to Business and Professions Code section 4051, subdivision (b).

Appropriate licensed entities and personnel are performing the functions as required and authorized by California pharmacy law. This process is different from the refill and central fill processes authorized by California Code of Regulations, title 16, sections 1707.4 and 1710.

It is the corresponding responsibility of every pharmacist and/or pharmacy filling a prescription to ensure legitimacy, propriety, and accurate dispensing.

ISSUE 2

California Central Prescription Processing Facility

Scenario: A prescription is sent electronically or via fax to a central facility to process the prescription and perform drug utilization review. This central facility is located in California and California licensed pharmacists are performing the review. This facility doesn't dispense prescription drugs. Once approved, the prescriptions are dispensed by a licensed pharmacy that may or may not have a shared ownership and common electronic prescription files with the central prescription processing facility.

Discussion:

Business and Professions Code section 4071.1 authorizes a pharmacist to electronically enter a prescription or order into a pharmacy or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital.

California Code of Regulations, title 16, section 1793.7 authorizes a pharmacy to employ a non-licensed individual (clerk-typist) to enter prescription information into a computer system, generate a prescription label and to receive and request refill information. These functions must be performed under the direction of a pharmacist.

At least one central prescription processing facility in California has been licensed as a pharmacy. The reason for licensure as a pharmacy is two-fold. First, the prescriptions are faxed to the facility for central processing. Because there is a fax copy of the prescription, it has been reasoned that the facility must be licensed as a pharmacy to accept the faxed prescription document. (Cal. Code Regs., tit. 16, section 1717, subd. (e)). It can be argued that Business and Professions Code section 4051, subdivision (b)(2) authorizes the pharmacist to have access to the prescription, patient profile or other relevant medical information. This section doesn't require that this information be electronic only. However, does this central facility have the authority to maintain the faxed copy of the prescription record once it has been processed and the pharmacist has approved it for filling? Does the pharmacist? What happens to the faxed prescription document? What are the record-keeping requirements for each prescription recipient?

The second reason that this facility is licensed as a pharmacy is so that it can employ non-licensed pharmacy personnel to process prescriptions as authorized by California Code of Regulations, title 16, section 1793.7.

However, this central prescription processing facility doesn't dispense prescription drugs, so the question is raised whether this central facility is appropriately licensed as a "pharmacy." California pharmacy law defines a "pharmacy" in part as "an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded." (Bus. & Prof. Code, § 4037, subd. (a)). This definition also states that a pharmacy includes, but is not limited to, "any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail." (*Ibid.*). Possession, storage, and sale of dangerous drugs or devices is therefore a central part, though not an explicitly necessary part, of the definition of a California "pharmacy."

California pharmacy law does not specifically define the scope of practice for the profession of pharmacy. That scope of practice has been defined in other sources. For instance, the National Association of Boards of Pharmacy in its *Model Act* defines the "Practice of Pharmacy" as: the interpretation, evaluation, and implementation of Medical orders; the Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Regimen Reviews, the Practice of Telepharmacy within and across state lines; Drug or Drug-Related research; the provision of Patient Counseling and the provision of those acts or services necessary to provide Pharmaceutical Care in all areas of patient care, including Primary Care and Collaborative Pharmacy Practice; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices and maintenance of proper records for them.

The issue before the Licensing Committee is whether or not the Board of Pharmacy

should license a “central prescription processing facility” located in California that does not dispense prescription drugs or devices as a “pharmacy.”

Business and Professions Code section 4051, subdivision (b), provides that a pharmacist may perform cognitive services outside of a pharmacy as long as the pharmacist has access to the records. For discussion purposes, the committee may want to consider amending this section to require that the pharmacist in the central processing facility who is performing these services outside the pharmacy maintain the patient records or other patient specific information used in these activities in a readily retrievable form and provide those records to the board upon request. This would include all faxed prescription documents and other records. The proposal would require the pharmacist to maintain patient records similar to that of a prescriber and the patient records may be different than the patient profile maintained by the pharmacy.

The committee may also want to seek clarification from counsel as to whether the law needs to be amended to allow a pharmacist to use a “non-licensed” individual to assist in the processing of prescriptions at a central location.

Another alternative for consideration would be to develop a special license category for the central prescription processing center that is not designated as a “pharmacy,” and therefore the facility isn’t given the authority to compound, purchase, store, or dispense prescription drugs and devices.

ISSUE 3

Central Prescription Processing Facility and/or Call Center Located Outside of California

Scenario: A prescription originates in California. It is sent electronically or via fax to an out-of-state central prescription processing facility. The out-of-state central prescription processing facility inputs the prescription label information and a pharmacist (who may or may not be licensed in California) performs drug utilization review. The prescription is filled and dispensed at a California pharmacy or through a California licensed nonresident pharmacy. Also, within the central prescription process facility, there may be a Call Center, where California patients can talk to a pharmacist and receive pharmacist’s services. In some instances, a Call Center may be stand-alone and not part of a central prescription processing facility.

Discussion:

The out-of-state central prescription processing facility may or may not be licensed in its resident state as a pharmacy. If it is licensed as a pharmacy in its resident state, the pharmacy does not meet the definition of a California nonresident pharmacy in that the pharmacy doesn’t ship, mail or deliver controlled substances, dangerous drugs, or dangerous devices into California.

Therefore, does an out-of-state central prescription processing facility have the authority to process prescriptions for California patients? Is this authority increased if the review process is performed or overseen by a pharmacist licensed in California? Does a non-California licensed pharmacist have the authority to perform drug utilization review and/or other pharmacist's services for California patients? Also, what authority or ability does the Board of Pharmacy have to protect the public if the out-of-state pharmacist is unprofessional in providing pharmacist's care to California patients? What would be the record-keeping requirements for each prescription recipient?

Under current law, a California licensed nonresident pharmacy may perform all these services for California patients without requiring California licensure for the pharmacist.

The Call Center may be required to be registered with the Telephone Medical Advice Services Bureau (Bus. & Prof. Code, § 4999 et. seq.).

ISSUE 4

Out-of-State Regional Call Center Database – Therapeutic Interchange

Scenario: A database for California pharmacies is maintained in or through a regional call center located and managed in another state. This regional call center is a licensed pharmacy in that state and is supervised by a licensed pharmacist from that state. It is unknown if this licensed pharmacy also dispenses dangerous drugs, either within its state or to California patients. The database identifies non-preferred drugs. These non-preferred drugs are identified for evaluation and consideration for therapeutic interchange and conversion to the company's preferred drug. The goal is to switch equally effective medications within a class to alternatives that are less costly.

A California licensed pharmacist reviews and approves the therapeutic interchange of a non-preferred drug with that of a preferred drug. Once approved by the California licensed pharmacist, the prescription is faxed to the California physician for approval or rejection. The physician faxes back the approval or denial to the our-of-state regional call center where the database is updated.

Discussion

While the regional call center is licensed as a pharmacy in its domestic state, it doesn't appear to meet the definition of a California nonresident pharmacy (e.g., it does not ship, mail or deliver drugs into California). Based on the information provided, it is a California licensed pharmacist who makes the determination whether or not a therapeutic interchange is appropriate for the California patient and if so, then the California prescriber is contacted to approve the change. Can a pharmacy not licensed in California, such as this regional call center (e.g., licensed in Texas) maintain and make use of a pharmacy database for California patients?

The Call Center may be required to be registered with the Telephone Medical Advice Services Bureau (Bus. & Prof. Code, § 4999 et. seq.).

ISSUE 5

Medication Therapy Management Programs Across State Lines

Consistent with the above scenarios, there is a provision in the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide Medication Therapy Management (MTM) for Medicare beneficiaries. Examples of MTM services are: patient health status assessments, medication "brown bag" reviews, formulating/monitoring/adjusting prescription treatment plans, patient education and training, collaborative drug therapy management, special packaging, refill reminders and other pharmacist related services.

Discussion

As pointed out in the comments provided by NABP to the Centers for Medicare & Medicaid Services on the proposed regulations to implement the MMA, NABP was not clear on how states will view the provision of MTMP's across state lines. Similar to the situations presented above, California needs to decide how it wishes to address pharmacists not licensed in California providing MTM to California patients.

Another possible issue is whether California should alter, expand or refine its scope of practice and/or provisions dealing with collaborative practice/medication management to respond to the MMA and the existence of the MTM reimbursement protocols. As noted above, for example, the definition of "pharmacy" in the NABP *Model Act* addresses the propriety of collaborative practice and provision of drug management services explicitly.

SUMMARY

Issues for Consideration by the Licensing Committee

1. Are any issues raised by inter-network pharmacy prescription processing?
2. How should a central processing prescription facility located in California that doesn't dispense prescription drugs or devices be regulated?
 - Should the facility be licensed as a pharmacy?
 - Should the facility be licensed as a "central processing prescription facility"?
 - Should such a facility be allowed?
 - Should the facility not be licensed, but require that the pharmacist maintain patient records for cognitive services? Should the pharmacist be allowed to use non-licensed personnel to assist in

the processing of prescriptions as is currently authorized in a licensed (dispensing) pharmacy?

- What are the record keeping requirements for each prescription recipient? Are the prescriptions being transmitted twice? First to the local pharmacy then to the central processing facility and then back to the dispensing pharmacy.
3. How should a central prescription processing facility located outside of California that processes prescriptions for California patients but doesn't dispense prescription drugs to California patients be regulated?
- Should the facility be licensed as a nonresident pharmacy?
 - Should the facility be licensed as a nonresident "central processing prescription facility"?
 - Should an out-of-state facility be allowed to process prescriptions for California patients?
 - What are the record keeping requirements for each prescription recipient? Are the prescriptions being transmitted twice? First to the local pharmacy then to the central processing facility and then back to the dispensing pharmacy.
4. Can a pharmacist not licensed in California perform cognitive services (Medication Therapy Management) for California patients?
- Can a pharmacist not licensed in California perform such services in a facility licensed in California as a nonresident pharmacy?
 - Should the pharmacist be licensed in California to perform such services for California patients?
5. Can an out-of-state pharmacy or call center (not licensed in California) maintain a central pharmacy database for California pharmacies and/or California patients? Who would have access to this database for California patients?

ATTACHMENT 3

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Alternative Pharmacy Practice Site

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Prescription Fulfillment Process

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Prescription Fill Process

Prescriptions attained via Mail, Fax or Electronic

All mailed documents and prescriptions are imaged

Front-End Processing

Pharmacist contacts physician and/or patient as necessary

Back-End Processing

Rx Filling

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Alpha Workstation Screen Shot - Order Completion / Verification

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Hub & Spoke Model

Remote Sites aligned with a single pharmacy permit

Pharmacist-in-charge will have oversight responsibility

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Prescription Fill Process

Prescriptions attained via Mail, Fax or Electronic

All mailed documents and prescriptions are imaged

Front-End Processing

Pharmacist contacts physician and/or patient as necessary

Back-End Processing

Rx Filling

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Work@home Program Management

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Program Goals & Objectives

Model the program after existing Work at Home initiatives: (e.g.: Federal & State)

- U.S. Office of Personnel Management taking into account Medco's needs.

Regulatory Compliance – State & Federal

- Work@home pharmacists will comply with all Federal and State regulations as required by law.

Patient Health & Safety Practice Standards will remain consistent

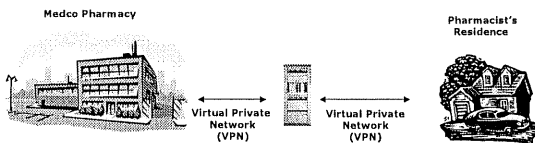
Medco Professional Standards of Pharmacy Practice

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Medco's Alternative Site System Technology Model



Virtual Private Network – (VPN)

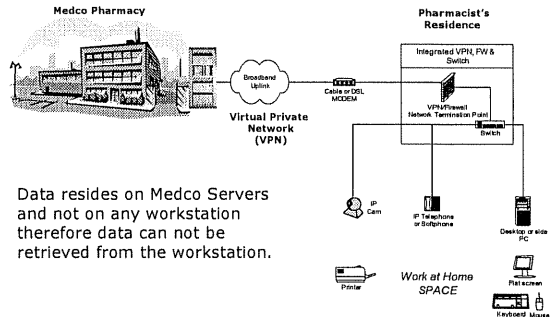
A set of authorized users on a public network such as the Internet that communicate among themselves using encryption technology so that their messages are as safe from being intercepted and understood by unauthorized users as if the authorized users were connected by private lines.

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Medco's Alternative Site System Technology



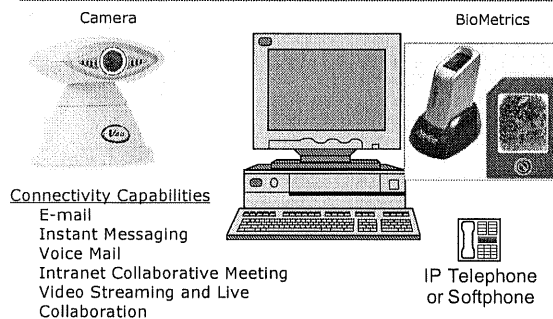
Data resides on Medco Servers and not on any workstation therefore data can not be retrieved from the workstation.

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Workstation - Capabilities

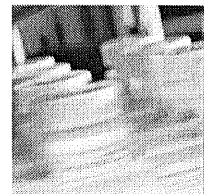


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Systems & Data Security



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System & Data Security

System Security – Data Transmission

Virtual Private Network – (VPN)

Internet Protocol Security - (IPSec) uses encryption technology to provide data confidentiality, integrity, and authenticity between participating peers in a private network.

3Des = Triple data encryption standard

Data Security –

- Data resides on Medco Servers and not on any workstation thus data can not be retrieved from the workstation.

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System Security

System Security – Workstation

User ID

- Each Pharmacist receives a unique UserID and is required to establish a password for identification and audit tracking

BioMetrics – Fingerprint Identification

Each pharmacist is authenticated by fingerprint each time a pharmacist logs onto the system

Lock-out process

- If no activity is detected, the system will automatically sign-off (lock-out) the pharmacist until the pharmacist goes through the sign-on process to re-establish connectivity

Home Security

- The systems will be under the custody of the pharmacist

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Quality Controls and Reporting



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Program Supervision

Supervision & Program Management –

Quality Assurance Monitoring Software

- Allows a supervisor to monitor an employee in "real-time" and "retrospectively"
- Retrospective recreation of entire sequence of events every screen shot down to the keystroke
- Utilized as a performance measurement tool
- Valuable tool in educating employees towards continual quality improvements
- Complete auditing capabilities on all transactions

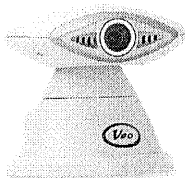
Audit program (Site visits & Remote)

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Proposed Camera



User can turn off camera.
Camera status is visible.
Remote operator can observe in real time or via periodic snap-shots.
Camera can be used in two way video calls.

Camera

Surveillance Mode – During the time the pharmacist is signed-onto the system a still shot every 5 seconds will record a photo.
Continuous Feed – To establish real-time connectivity for education and visual communications (ie: Q&A with Supervisor)

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Program Supervision

Metrics & Control Processes

- Quality – Medication Errors- compare the number of errors created by a pharmacist compared to:
 - Other pharmacists in alternate sites
 - Pharmacists in a control group
 - Compared to pharmacist history (if available)

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Measures, Metrics and Reporting

Workflow and Prescription Processing Measurements

- Number of Prescriptions processed
- Number of Pharmacists
- System Transmission efficiency compared to control

Quality of Prescription fill

- Compare the number of Medication Errors with pharmacists working from home vs. pharmacists working in "brick and mortar" facilities.
- Variance in SOPs compliance (Home Pharmacist vs. Control Group)

Statutory and Regulatory Compliance

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Professional Education



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Professional Education

Professional Education

- Quality Training Program
 - Didactic (live or recorded)
 - Self-Study
 - Technology - Computer-based training
 - Competency Assessment with corrective education
- Continuing Education

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Background Material



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Approvals to date

Texas - no restrictions

- 291.36 Central Prescription or Medication Order Processing
 - 1- The purpose of this section is to provide standards for centralized prescription drug or medication order processing by a Class A (Community), Class C (Institutional), or Class E (Non-Resident) pharmacy.
 - 2- Any facility established for the purpose of processing prescription drug or medication drug orders shall be licensed as a Class A pharmacy under the Act. However, nothing in this subsection shall prohibit an individual pharmacist employee who is licensed in Texas from receiving or receiving the pharmacy's electronic data from outside the pharmacy in order to process prescription or medication drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

New Jersey - 20 pharmacist pilot beginning 11/29/04

Ohio - Pilot approved, no restrictions on number, in planning phase

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Image Technology - Key Attributes

Retention/Retrieval

- Available on-line for defined period of time
- Readily retrievable

Unalterable

Workstation provides robust "user tool box" to enhance image for ease of readability and fraud detection

- Image Rotate and Zoom Options- reduce, magnify and "fit to page"
- Image Background Color- Changes the background of the image (i.e., checking altered prescription images)

Ability to append annotations/notes to image

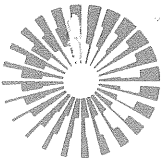
Better than paper!!!

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ATTACHMENT 4



Omnicare

Omnicare, Inc.
1600 RiverCenter II
100 East RiverCenter Boulevard
Covington, Kentucky 41011
859/392-3300
859/392-3333 Fax

RECEIVED BY CALIF.
BOARD OF PHARMACY
2005 MAR -1 PM 2:24

February 28, 2005

Ms. Patricia Harris
Executive Officer
California State Board of Pharmacy
400R Street, Ste. 4070
Sacramento, CA 95814-6237

RE: Written Comments for March 16th Licensing Committee Meeting

Dear Ms. Harris,

Please accept this letter and the attached document as our statement of support for the concept of requiring a contract between a California Licensed Pharmacy and our Regional Clinical Center.

I would also like to appeal for the Committee and Board to move quickly as the Medicare Modernization Act and Part D Medicare are scheduled to begin January 2006.

Please do not hesitate to call or request my attendance at a future meeting to answer questions.

Sincerely,

William A. Fitzpatrick, R.Ph.
Corporate Compliance Officer
Omnicare, Inc.
100 East RiverCenter Boulevard, Suite 1500
Covington, KY 41011
Phone (859) 392-3334
Fax (859) 392-3320
bill.fitzpatrick@omnicare.com

Regional Clinical Center Overview

The purpose of the Regional Clinical Center (RCC) is to provide ancillary support to the pharmacies for communicating to outside parties (physicians, facilities, etc.) through the use of centralized data access combined with automation technology. By centralizing these functions, we can centralize the expertise related to these programs, reduce redundancy in technology expenditures, and reduce pharmacy workload to allow the pharmacies to concentrate on core activities.

Currently, the Southwest Region RCC is utilized to support the management of programs for Therapeutic Interchange (TI), Preferred Drug Lists (PDL), CII Rx requisition and tracking, Prior Admission Drug Cost Analysis, as well as specific activities in therapy management for some drug products. Most of our programs are handled according to the following flow – obtain data from the pharmacy systems, run data through a database to identify candidate transactions, generate mail merge communications to the appropriate parties, fax server distribution of documents to appropriate parties. All of these documents are bar-coded to facilitate the tracking process once these documents are returned to the RCC. All information communicated to the RCC is tracked in the database, then forwarded to the pharmacies (both positive and negative responses).

There is a feedback system in place for the pharmacies to identify exclusions to the process on either an individual prescriptions basis or a more general basis (exclude certain physicians, facilities, therapeutic interchange initiatives, etc.). Each physician also has a profile indicating his/her preferences (method of contact of choice, inclusion or exclusion of initiatives, etc.). We also receive input from our clinical associates related to the processes employed by the RCC.

Patient information is utilized in a variety of ways for the different processes. For example, patient allergy information is screened for the TI process, patient identifier information is used for the CII requisition process (DOB, SSN, etc.).

We first implemented the RCC in October 2002 to support the TI programs for the pharmacies. Since that time, there has been a steady growth in opportunity to utilize the services and technologies of the RCC. We are seeing more state Medicaid programs and more third party programs move in the direction of PDL's. Currently, we are seeing a lower than expected use of the Medicare Discount Cards. As this situation changes in January 2006 with the implementation of the Medicare Part-D program, we anticipate an increasingly complicated environment in which we will be called on to manage a variety of PDL programs. Electronic access to patient information to provide a more comprehensive clinical assessment will also be key in this process.

Because of the enormous cost implications of poorly managing this process, there will be an increasingly important role for the RCC's to play in supporting the pharmacies in the management of these programs.